K022342

OCT 0 9 2002

510(k) Summary

Anzai eZ-Scope AN Portable Gamma Camera

Common/Classification Name: Gamma Camera, 21 CFR 892.1110

Anzai Medical Company, Ltd.
3-6-25 Nishi-Shinagawa
Shinagawa-ku
Tokyo 141-0033
Japan

Contact: T. Kaneko, Prepared: July 17, 2002

A. LEGALLY MARKETED PREDICATE DEVICES

The **eZ-Scope AN Gamma Camera** is substantially equivalent to the currently marketed **eZ-Scope AN Gamma Camera**, which was cleared by FDA on May 28, 2002 as K020643. For the new indication for use, intraoperastive use, it is also substantially equivalent to the Neoprobe 2000 Isotope Probe (based on K971320 for the Neo 1500).

B. DEVICE DESCRIPTION

The **Anzai EZ-Scope AN Portable Gamma Camera** is a currently marketed portable gamma camera, utilizing a solid state detector, rather than a scintilator, to detect gamma rays. The cadmium-zinc-tellurium detector allows sharp energy discrimination and spatial resolution. The detector array is made from pixelized cadmium-zinc-telluride (CZT) crystals, with each of the 256 pixels having dimensions of 2 x 2 mm. The system is available in two configurations, **eZ-Scope AN** and **eZ-Scope Light**. These differ primarily in the computer, the former model using a desktop computer and the latter a laptop. In the desktop version, the computer is mounted on a cart, while the laptop version does not have a cart.

The present 510(k) is for an addition to the indications for use statement (see next section) pertaining to intraoperative use. The user manual has been modified to include instructions for disinfecting the camera head and covering it with a protective plastic sheath to prevent contamination of a sterile field in case of an accidental puncture of the sheath during intraoperative use.

C. INTENDED USE

The Anzai eZ-Scope Portable Gamma Camera is indicated for use to

image the distribution of radionuclides in the human body using planar imaging techniques. The eZ-Scope may be used intraoperatively or on pathological specimens if a protective sheath is used.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **eZ-Scope** is a medical device, and it has the same indications for use, except for the addition of the phrase pertaining to intraoperative use, as the currently marketed version of the device. The indications for use for the Neoprobe gamma detector cover the indication for intraoperative use. The intended diagnostic effect is the same as the predicate devices. The **eZ-Scope** has the same (identical) technological characteristics as the currently marketed device.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same as those of the currently marketed **eZ-Scope**.

F. TESTING

No new performance testing was necessary for the present submission.

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Anzai Medical Company, Ltd.
% T. Whit Athey, Ph.D.
Senior Consultant
Health Policy Resources Group, LLC
2305 Gold Mine Road, Suite 200
BROOKVILLE MD 20833-2233

Re: K022342
Trade/Device Name: Anzai EZ-Scope AN
Portable Gamma Camera
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: I
Product Code: 90 IYX
Dated: July 17, 2002
Received: July 18, 2002

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K 022342

Device Name: Anzai eZ-Scope Portable Gamma Camera

Indications For Use:

The Anzai eZ-Scope AN Portable Gamma Camera is indicated for use to image the distribution of radionuclides in the human body using planar imaging techniques. The eZ-Scope may be used intraoperatively or on pathological specimens if a protective sheath is used.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022342